PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200301957 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00792	International filing date *(day/month/year)* 19.11.2003	Priority date *(day/month/year)* 19.11.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/0215		
Applicant RHINOMETRICS A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.06.2004	05.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kempin, H-F Telephone No. +49 89 2399-2716

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00792

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

2-9	as originally filed
1, 1a	filed with telefax on 12.11.2004

Claims, Numbers

1-5	filed with telefax on 12.11.2004

Drawings, Sheets

1/3-3/3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 6

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☐ claims Nos.

   because:

   ☒ the said international application, or the said claims Nos. 3-5 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,2
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1,2
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1,2
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inv ntive step and industrial applicability

As already indicated in the International Search Report, **method claims 3-5** (claims 4-6 before amendment) relate to a diagnostic method practised on the human or animal body since the method comprises the step of obtaining information on the body cavity, which information is directly related to occlusions or deformations of the body cavity (see the description on page 1, lines 13, 14). Consequently, this International Preliminary Examining Authority is not required to carry out an international preliminary examination for these claims (Rule 67.1(iv) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
   D1: US-A-5 882 314 (LOUIS BRUNO ET AL) 16 March 1999,
   D2: US-A-5 823 965 (RASMUSSEN STEEN BARBRAND) 20 October 1998

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

A device for examining human and animal body cavities (see column 1, lines 3-8) comprising
-a catheter having a proximal end and a distal end ('closed' should have been deleted) for inserting into the human or animal body cavity, the catheter having a lumen extending from the proximal end into the catheter (see 16 in figure 1),
-a signal generator for generating an excitation signal (see 28, 34, 38),
-a transmitting transducer (see 22) coupled to receive the excitation signal and arranged to transmit, in response to the excitation signal, a corresponding acoustic signal into the lumen of the catheter (see column 3, lines 9-12), and
-a receiving transducer arranged to receive reflections of the acoustic signal from the lumen of the catheter (see either 18 or 20).

The device of claim 1 therefore differs from this known device in that the distal end of the catheter is closed and the device further comprises the features of the last paragraph of claim 1. The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to improve the known device by enlarging its measurement capabilities.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
The use of a catheter with a closed end in the device of D1 does not contribute to inventive step since a close end catheter is already used in a similar device; see document D2, figure 1, references 1 and B. However, the available prior art does not disclose or suggest to use a pressure transducer sensitive to frequencies lower than 100 Hz and to process such low-frequency pressure variations. This allows the measurement of parameters as described in the last paragraph on page 2 of the present application. In document D1 the sensed signals are filtered by a bandpass filter of 100 Hz to 10 kHz. Document D2 proposes to work with an infrasound band of up to 200 Hz.

Claim 2 is dependent on claim 1 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

Further observation
It is noted that a passage of the description is missing on page 6 after line 20. The description jumps from figure 1 to figure 4.

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DEVICE AND METHOD FOR MEASURING IN BODY CAVITIES

Background of the invention

The invention relates to the examination and measurement of passages and cavities in the human or animal body, and in particular of irregularities such as constrictions by means of a device comprising an electrical signal source, a catheter to be introduced into a cavity through a natural or surgically prepared opening in the body, a first transducer for transmitting an acoustic activation signal from the signal source to and through the catheter, a second transducer for reception of response signals from the catheter, and a computer for analysing the response signals in relation to the activation signal.

Various methods are known for the examination and measurement of occlusions, deformations, movements etc. in various human and animal cavities, e.g. airways such as the pharynx and the larynx, the gastro-intestinal tract, the urinary system, blood vessels etc.

US 5 823 965 discloses an apparatus and method for examining human or animal body cavities such as airways and the gastro-intestinal tract. The device has a flexible hose-like catheter, which is introduced into the cavity with the distal end of the catheter beyond the zone to be examined. An acoustical excitation signal is sent into the interior of the catheter. Irregularities reflect the acoustical signal, which is picked up by a receiving transducer and analysed. Such method is often referred to as reflectometric examination. A computer displays results of the examination on a screen. The device may comprise means for establishing a positive static pressure with the purpose of dilating the flexible wall of the measuring zone.

~~The purpose of the invention is to provide improvement in the measuring capability in such known devices.~~

US 5 882 314 discloses the use of a catheter with an open distal end. Sound pulses are emitted into a body cavity, and the reflected signals are measured to extract information on the geometry of the body cavity. The frequency range is limited to 100 Hz - 1 kHz.

The purpose of the invention is to provide improvement in the measuring capability in such known devices.

CLAIMS

1. A device for examining human and animal body cavities, the device comprising

- a catheter (1) with a proximal end (A) and a closed distal end (B) for inserting into the human or animal body cavity, the catheter having a lumen extending from the proximal end into the catheter,

- a signal generator (2) for generating an excitation signal,

- a transmitting transducer (3) coupled to receive the excitation signal and arranged to transmit, in response to the excitation signal, a corresponding acoustic signal into the lumen of the catheter,

- a receiving transducer (5) arranged to receive reflections of the acoustic signal from the lumen of the catheter, and

- a pressure transducer (42) sensitive to ~~low~~ frequencies (the catheter is lower than 100 Hz, preferably lower than 10 Hz) and arranged to sense, when inserted into the body cavity, the pressure in the lumen of the catheter and outputting a signal representing low-frequency pressure variations ~~and~~ to be received and processed by the signal processing device (4, 6).

- a signal processing device (4, 6) for receiving and analysing the output signals from the receiving transducer (5), ~~and the pressure transducer (42)~~

2. A device according to claim 1 wherein the excitation signal comprises an impulse signal of duration short enough to make the corresponding reflected signal distinguishable from the excitation signal.

characterized in that the distal end (B) of the catheter (1) is closed, and that the device further comprises

~~3. A device according to claim 1, where the pressure transducer (42) is sensitive to frequencies up to at least 10 Hz, preferably up to at least 100 Hz.~~

3 4. A method for obtaining dynamic data of the conditions in a human or animal body cavity, the method comprising

- transmitting an acoustic impulse signal into the body cavity,

- receiving reflections of the acoustic impulse signal from the body cavity,

- obtaining data of low frequency pressure changes at frequencies lower than 100 Hz, preferably lower than 10 Hz in the body cavity, and

- analysing the received reflections and the data of low frequency pressure changes to obtain information on the body cavity.

4 5. A method according to claim 3 comprising transmitting the data obtained to a signal processing device for simultaneous processing.

5 6. A method according to claim 3 wherein the analysis of the received reflections and of the data of low frequency pressure changes are used to provide corresponding area and pressure representations.